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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CFN 1110148

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

October 20, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John B. Graham, Jr., President
Graham & Rollins, Incorporated
509 Bassette Street
Hampton, Virginia 23669

Dear Mr. Graham:

During an inspection of your facility conducted by the Food and Drug Administration on September 23 and 25, 1997, in-line subsamples of fresh picked crabmeat were collected and analyzed for Listeria monocytogenes (L. mono.). The analysis revealed the product to be positive for L. mono. As a result, the product is adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the bacterium L. mono. may have rendered the food injurious to health. On October 3, 1997, you were sent a report of sample analysis signed by William Ment, Science Branch Director, informing you of these findings.

In addition, during our inspection, several insanitary conditions were observed in your facility. These were listed on an Inspectional Observation form (FDA-483) and presented to Terry L. Graham, Vice President, at the close of the inspection. Food processed under insanitary conditions is adulterated per Section 402(a)(4) of the Act, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

We understand that you have agreed to thermally process the crabmeat produced on September 23, 1997, and that this thermal processing is designed to destroy pathogenic microorganisms. Note that L. mono. can survive in a food processing plant environment. As a result, your facility may be a potential continuing source of this pathogenic microorganism which may contaminate future foods processed in your plant. It is your responsibility to assure continuing adherence with the requirements of the Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations, Part 110.

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You should take prompt action to correct these violations. Failure to do so may result in regulatory action, such as seizure and/or injunction, without further notice.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Loveen M. Beck

Acting Director, Baltimore District

cc: Virginia Department of Health
Division of Shellfish Sanitation
Suite 109
1500 East Main Street
Richmond, Virginia 23219